UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

YE ZHOU, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. NEXTCURE, INC., MICHAEL RICHMAN, STEVEN P. COBOURN, KEVIN N. HELLER, M.D., DAVID KABAKOFF, PH.D., ELAINE V. JONES, PH.D., CHAU Q. KHUONG, JUDITH J. LI, BRIGGS MORRISON, M.D., TIM SHANNON, M.D., STEPHEN WEBSTER, STELLA XU, MORGAN STANLEY & CO. LLC, BOFA SECURITIES, INC., PIPER JAFFRAY & CO., NEEDHAM & COMPANY, LLC, and BTIG, LLC, Defendants.	Case No. 1:20-cv-07772-LTS-RWL **ORAL ARGUMENT REQUESTED**

PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE AMENDED COMPLAINT

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INTRODUCTION

This is a securities class action arising under the Securities Exchange Act of 1934 (the "Exchange Act") and the Securities Act of 1933 (the "Securities Act") challenging misstatements and omissions concerning NextCure, Inc. ("NextCure"), a clinical-stage biopharmaceutical company, during the period from May 8, 2019 to July 13, 2020 (the "Class Period").

During the Class Period, Defendants repeatedly misled investors regarding the potential of NC318, NextCure's leading cancer treatment, and the Company's FIND-IO development platform. According to Defendants, the Company's Phase I trial had generated "very encouraging" results, including one patient that "achieved completion remission," and the Company was headed full steam toward Phase II testing. Further, Defendants represented that the Company's FIND-IO development platform was a "proprietary" technology that gave the Company a competitive advantage in developing new treatments.

The truth was NextCure's Phase I trial had been a complete disaster. The trial was poorly designed and generated data that was both disappointing from an efficacy standpoint and corrupted by the study's flawed protocols. Contrary to Defendants' representations, NC318 had no realistic path forward because: (i) the Phase I trial was extremely small; (ii) the patients with the two best results were not biopsied before treatment, meaning one could not discern whether NC318 was the reason for the positive results; (iii) the study was open to patients who had recently received other cancer treatments, making it difficult to assess causation; and (iv) the overall responsiveness level was low, indicating a critical lack of effectiveness and compounding the flaws in the study that made effectiveness difficult to assess. Defendants had all of this information by early November 2019 and so knew that the "writing was on the walls," but professed false optimism because they

needed to maintain the charade that NC318 was still viable so that the Company could complete a $172.2 million secondary offering on November 18, 2019.

On July 13, 2020, the Company abruptly walked away from the NC318 trial for its most commercially important cohort – non-small cell lung cancer (NSCLC) cancer – and admitted that its decision was "based on the current enrollment criteria and clinical response data." ¶12; Def. Ex. L. In other words, the Phase I data that the Company had been relentlessly touting since November 2019 was, in reality, so bad and so flawed that the Company could not proceed to Phase II. The Company also announced the departure of its Chief Medical Officer, Defendant Heller, who had run the trials and who made many of the misstatements at issue in this case. On this news, the price of NextCure's stock dropped 54%.

Defendants argue in support of their motion to dismiss ("MTD Br.") that their statements amount to nothing more than "puffery." But that is not the case. The securities laws are clear that false optimism of the sort Defendants engaged in here is actionable. A pharmaceutical company cannot make rosy claims about being on track to develop a blockbuster cancer treatment when it knows otherwise. None of Defendants' remaining arguments have merit.

Accordingly, the Court should deny Defendants' Motion to Dismiss in full.

BACKGROUND

A. NextCure and the Find-IO Platform

NextCure is a clinical-stage biopharmaceutical company aiming to discover and develop immune-oncology therapies. ¶3.[1] NextCure strives to produce cancer immunotherapy that restores an impaired immune system to a healthy state by detecting and killing cancerous cells

[1] Unless otherwise indicated, all "¶" and "¶¶" citations are to the Amended Complaint ("AC" or the "Complaint"); capitalized terms have the same meaning as set forth in the AC; emphasis is added; and internal citations are omitted.

while avoiding harming healthy cells in the process. ¶32. NextCure's approach to identifying targets for new immunomedicines is based on its FIND-IO platform, which is a screening system that "identif[ies] human proteins" using this information "to determine whether those proteins alter or stop an immune response resulting in immune evasion." ¶33.

B. NextCure's Leading Treatment Candidate Was NC318

NC318 was presented as a treatment that could reduce and kill tumors by blocking the S15-mediated immune suppression and restoring T cell function and anti-tumor immunity in the tumor microenvironment, or TME. ¶37. NextCure announced that it expected NC318 to improve outcomes for the estimated 60%-70% of patients who had failed to respond to existing cancer therapies, including blockbuster drugs like Merck's KEYTRUDA and Bristol-Myers Squibb's OPDIVO. ¶38. To fulfill any promises, the drug would need to be approved by the FDA.

C. NextCure's Deeply Flawed Phase 1/2 NC318 Clinical Trial and Problematic Data

In October 2018, NextCure initiated the first-in-human, open label trial for NC318 to assess NC318 in patients suffering from Head and Neck Squamous Cell Carcinoma, NSCLC, Ovarian Cancer, and Triple Negative Breast Cancer, among other afflictions. ¶¶40-42. Though the Phase 1/2 Clinical Trial was purportedly designed to assess the safety, tolerability and preliminary efficacy of NC318 (¶43), the study was riddled with problems, rendering the data only useful if a high rate of durable responses was observed. ¶55.

Unfortunately, the data was disappointing and, when combined with flaws in the study design, meant that there was no viable path forward for the NSCLC cancer cohort. NextCure had collected its Phase I trial data by early November 2019. *See* ¶¶48-49. The overall response rate ("ORR") for NSCLC was only 15%, meaning 15% of NSCLC patients who had received that treatment responded. ¶49. This ORR is very low in the context of a clinical trial examining a

treatment for NSCLC. When the FDA has relied on ORR to approve drugs for treatment of NSCLC, it has generally required an ORR in the range of 33% to 66%. ¶55. The value of this already weak data was further undermined by the small sample size. With only ten patients in the NSCLC study, the lower bound of the confidence approached zero. ¶56. Further, even the limited positive data available was essentially useless because it was contaminated due to the study's flawed protocols. ¶¶57-59. As was later revealed, the two NSCLC patients who supposedly showed complete or partial responses were not biopsied prior to receiving NC318 treatment, meaning NextCure could not prove that the high over expression of S15 led to the responses. ¶57; *see also* ¶¶52-53. Further, the value of the data was undercut by the enrollment of patients who had recently received other cancer treatments. ¶58. Patients could be enrolled for the study even if they had recently received chemotherapy or monoclonal antibody treatment. *Id*. Moreover, since the study lacked any adequate measure to minimize bias on the part of both patients and investigators, its outcome measurement, "tumor response," which FDA Guidance explicitly warns about using to assess results in open-label trials, was likewise unreliable and, worse, incapable of translating into a "clinical benefit" that the FDA could base NC318's approval on. ¶¶53-54, 57.

D. NextCure's IPO and SPO

NextCure's IPO was on May 9, 2019, selling 5.75 million shares of NextCure common stock at $15 per share, for $86.5 million in proceeds. ¶¶127-28. On November 18, 2019, NextCure had a secondary offering, selling $172.2 million in stock at an offering price of $36.75 per share. ¶¶147-49. NextCure's ability to complete this large secondary offering depended on maintaining the market perception that NextCure was proceeding successfully to a Phase II NC318 trial for NSCLC. The commercial opportunity for NC318 was in NSCLC, a large market that supported

other blockbuster drugs such as Keytruda. ¶¶5, 49 (describing how NSCLC was a "large market opportunity"). Without that possibility, NC318, and thus NextCure, was worth far less. *See* ¶73.

E. Defendants Misleadingly Hyped NC318's Prospects and the FIND-IO Platform

Despite being fully aware that NC318 had hit a wall, Defendants elected to tout NC318's promise by citing selective results that made it appear the treatment was effective and on track for Phase II. In particular, Defendants repeatedly celebrated the supposed "meaningful responses" observed in two NSCLC patients, highlighting each, for example, in the November 5, 2019 abstract, which also included the misleading claim that NextCure witnessed an observed response ratio (ORR) in NSCLC patients of 27% and a disease control ratio (DCR) of 71%. ¶¶48-49. Indeed, Defendant Heller misleadingly claimed that the complete response was a "***direct result*** of NC318." ¶62. Defendants also repeatedly claimed that the results were "encourag[ing]" and "support the potential of NC318." ¶¶50-51. In so doing, Defendants misleadingly led investors to believe that the Phase I data was positive and that the Company was moving toward Phase II for NSCLC when, in fact, they knew that the Company was going to end the study. ¶¶52-59, 72.

Defendants added to this seemingly positive narrative by hyping NextCure's FIND-IO platform, which served as the sole driver behind a November 2018 multi-year collaboration agreement with Eli Lilly – an agreement that was singularly responsible for all revenue recognized by the Company. ¶¶36, 133. Embedded within the IPO and SPO offering materials were Defendants' numerous claims that NextCure's FIND-IO platform was "novel," "unique," and "proprietary" (¶¶3, 45-46), was developed, industrialized and optimized through "the immunological expertise of [NextCure's] management team" as well as other institutional "immunology knowledge, experience[,] capacities and tools[,]" (¶¶35, 46) and was responsible for

identifying the immunosuppressive properties of Siglec-15, the target of NC318, through NextCure's "proprietary approaches." ¶34.

F. NextCure Walks Away from NC318 Based on the Data from Phase I

Defendants maintained the appearance of moving forward for several months after the secondary offering. However, on July 13, 2020, the Company abruptly walked away from the NC318 trial for NSCLC. The Company admitted at the time that the basis for its decision was the bad data from Phase I that the Company had spent the previous eight months celebrating, stating that its decision to discontinue was "based on the current enrollment criteria and clinical response data." Def. Ex. L; ¶¶12, 72. It was also announced that Defendant Heller, who oversaw the entire study, including the clinical trial strategy for NC318, and who made (or authorized the making of) statements touting the Phase I data was stepping down from his leadership role. ¶72. Analysts slashed price targets and expressed serious concern, concluding, for example, that "the probabilities of [NextCure's] efforts developing lead program NC318 monotherapy in NSCLC & ovarian cancer [are now] ***0%***[,]" and further, that the news was simply "***unquestionably bad***." ¶¶73-79. The price of NextCure's shares plummeted over 54% in a single day. ¶78.

ARGUMENT

A. Legal Standards

"To survive a motion to dismiss, a complaint must contain sufficient factual matter accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A court must "accept all factual allegations in the complaint as true," *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007), and draw "all reasonable inferences in the plaintiffs' favor," *Giunta v. Dingman*, 893 F.3d 73, 78-79 (2d Cir. 2018); *In re Solv-Ex Corp. Sec. Litig.*, 210 F. Supp. 2d 276, 282 (S.D.N.Y. 2000).

1. Exchange Act Violations

Under "§10(b) and the corresponding Rule 10b-5, a plaintiff must plead that the defendant, in connection with the purchase or sale of securities, made a materially false statement or omitted a material fact, with scienter, and that the plaintiff's reliance on the defendant's action caused injury to the plaintiff." *Ganino v. Citizens Utilities Co.*, 228 F.3d 154, 161 (2d Cir. 2000). The statement "must be 'an actual ***statement*** [] [made] that is either untrue outright or misleading by virtue of what it omits to state'" – that is, an untrue statement or a "half-truth." *In re Glob. Brokerage, Inc.*, No. 1:17-CV-00916-RA, 2019 WL 1428395, at *8 (S.D.N.Y. Mar. 28, 2019) (quoting *In re Vivendi, S.A. Sec. Litig.*, 838 F.3d 223, 239 (2d Cir. 2016)) (emphasis in original). Plaintiff must also plead facts supporting a strong inference of scienter. *Ganino*, 228 F.3d at 169 (the court does not "require 'great specificity' provided the plaintiff alleges enough facts to support 'a strong inference of fraudulent intent.'").

2. Securities Act Violations

"Section 11 . . . allows purchasers . . . to sue certain enumerated parties in a registered offering when false or misleading information is included in a registration statement." *Herman & MacLean v. Huddleston*, 459 U.S. 375, 382 (1983). The provision is "limited in scope" and "places a relatively minimal burden on a plaintiff." *Id.* "If a plaintiff purchased a security issued pursuant to a registration statement, ***he need only show a material misstatement or omission to establish his prima facie case***. Liability against the issuer of a security is virtually absolute even for innocent misstatements." *Id*. Since scienter is not an element, §11 claims are governed by Rule 8(a), which only requires "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8; *Litwin v. Blackstone Grp., L.P.*, 634 F.3d 706, 715 (2d Cir. 2011). "'[A] well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof

of those facts is improbable, and that recovery is very remote and unlikely.'" *New Jersey Carpenters Health Fund v. Royal Bank of Scotland Grp., PLC*, 709 F.3d 109, 125 (2d Cir. 2013).[2]

B. The Amended Complaint Pleads Material Misstatements

1. Defendants Expressed False Optimism When They Knew that NC318 Could Not Progress to Phase II for NSCLC

From November 2019 onward, Defendants knew that there was no path forward to a Phase II trial for NSCLC. But rather than disclose that fact, Defendants continued to express false optimism about the data and they pretended as though NextCure was moving forward to Phase II. Thus, according to Defendant Heller, the data from Phase I showed some "***very encouraging promise.***" ¶51. Defendants made many similar statements. *See, e.g.*, ¶50 (stating company was "encourage[d]" and that the "results to date support the potential of NC318" and describing NC318 as having demonstrated "anti-tumor activity" that "reinforces" NextCure's "belief that NC318 has the potential to be the new therapy for patients with solid tumors"); ¶51 (stating that "[we] also are of course very encouraged by the confirmed responses in non-small cell lung" and discussing the plans for "phase 2").

Defendants also continued to misleadingly claim that NC318 had caused a remission in one patient and a partial remission in another despite the fact that, due to the study flaws, this could not be established and, relatedly, that these two data points did not indicate that NC318 had a path forward. For example, on January 16, Defendant Richman stated that "***most importantly was this***

[2] Although Defendants argue that the Section 11 claims sound in fraud and are therefore required to present allegations with the heightened pleading requirement under Rule 9(b) under the PSLRA because the claims sound in fraud, this is not the case. The mere fact that Plaintiff has also pled fraud claims does not subject her Section 11 claims to Rule 9(b). *Lewy v. SkyPeople Fruit Juice, Inc.*, No. 11 Civ. 2700 PKC, 2012 WL 3957916, at *8 (S.D.N.Y. Sept. 10, 2012). Rather, Rule 8 applies because the AC divided the claims under 10(b) and Section 11, and "this careful division makes it easy to distinguish between the two, and the substance of the allegations keeps the distinction as clear as does the complaint's structure." *In re Refco, Inc. Sec. Litig.*, 503 F. Supp. 2d 611, 632 (S.D.N.Y. 2007).

complete response" and "***[w]e have a predictable PK profile efficacy, looking at the CR, the PR and the 3 stable disease in non-small cell lung cancer***." ¶62. Defendant Heller completed the misleading picture by stating that the data "significantly supports that this was a direct result of NC318." *Id*. However, the two NSCLC patients who supposedly showed complete or partial responses were not biopsied prior to NC318 treatment, meaning NextCure could not draw these types of conclusions. ¶57. Sometimes cancer patients get better, either naturally or because of other treatments. ¶¶58-59. Therefore, it was misleading to indicate that NC318 was ***causing*** improvements when the data did not support that finding. *Id*.

It was also misleading for Defendants to claim to be "very encourage[d]" by the results of the Phase I trial when, in fact, they knew that the meager results combined with study flaws meant that the trial had failed. As the Second Circuit has opined, public companies' discussion of medical data is highly material to investors because "[t]echnical information about the medical efficacy of new drugs . . . has an obvious bearing on the financial future of a drug company. In an economy that produces highly sophisticated products, technical information is of enormous importance to financial analysts, whether such companies are producing drugs, as here, or nuclear power plants." *In re Carter-Wallace, Inc. Sec. Litig.*, 150 F.3d 153, 156 (2d Cir. 1998).

Accordingly, courts have repeatedly recognized that pharmaceutical companies cannot lead investors to believe that all is well with a potential new treatment when they are aware of facts to the contrary. For example in *In re Ariad Pharms., Inc. Sec. Litig.*, 842 F.3d 744, 753 (1st Cir. 2016), the court found that plaintiffs had adequately alleged actionable misstatements when they promoted a drug, reporting "in pertinent part, that 'management continues to be optimistic about ponatinib's prospects for approval in the U.S. . . . with a favorable label'" at the time it was in discussions with the FDA about concerns relating to side effects and the FDA had rejected the

"favorable label" language that the company had sought. The court held that "[w]hile management may have held out hope of achieving this result, the ***expression of that hope without disclosure of recent troubling developments created an impermissible risk of misleading investors***." *Id.* *See also In re Immune Response Sec. Litig.*, 375 F. Supp. 2d 983, 1019 (S.D. Cal. 2005) ("Plaintiffs do not allege that Defendants' public statements were knowingly false in the sense that they reported fictional clinical findings supporting REMUNE's efficacy. Rather, Plaintiffs allege that Defendants committed fraud by publicly reporting results that they knew or should have known were either so incomplete or so statistically flawed as to lack clinical significance. In other words, Plaintiffs' criticism is not that what was said was inaccurate, but that it was incomplete, thus portraying the results of the clinical trial in an unduly optimistic light."); *In re Neopharm, Inc. Sec. Litig.*, No. 02-2976, 2003 WL 262369, at *11 (N.D. Ill. Feb. 7, 2003) ("[I]f NeoPharm had knowledge that the Phase II trials were failing . . . then the pre-January 12 statements may very well have been misleading to investors."); *id.,* at *13 (holding that "the failure to disclose the news regarding Phase II . . . was materially misleading."); *In re Regeneron Pharms., Inc. Sec. Litig.*, No. 03 Civ. 3111 RWS, 2005 WL 225288, at *21 (S.D.N.Y. Feb. 1, 2005) ("in the context of a drug development program, courts have noted that '[s]tatements regarding the overall efficacy of the drug . . . cannot be simply dismissed as immaterial.' '[I]t would be a sad day when [a] court could determine that misstatements about whether a company's primary product worked did not alter the 'total mix' of information available in the market.'").

Furthermore, "[e]ven if a statement of opinion is literally accurate – *i.e.*, it is honestly held – it may still be actionable if the opinion omits facts necessary to make the statement not misleading to a reasonable investor." *Micholle v. Ophthotech Corp.*, No. 17-CV-210 (VSB), 2019 WL 4464802, at *7 (S.D.N.Y. Sept. 17, 2019). Here, it was misleading for Defendants to claim

to be encouraged by the results of the Phase I without disclosing the serious design flaws that rendered the data unusable and foreclosed progression to Phase II.

Defendants argue these statements were non-actionable puffery, but that is not the case. First of all, Defendants' contention that the Second Circuit has held that the words like "very encouraging" are always puffery is clearly wrong at a matter of law. *See* MTD Br. at 13-14. To the contrary, there is no categorical rule about some words always constituting "puffery"; puffery analysis is a highly fact-specific inquiry that turns on whether the challenged statement can be construed as a material misstatement. *Gross v. GFI Grp., Inc.*, 162 F. Supp. 3d 263, 268 (S.D.N.Y. 2016) ("Statements are not puffery if shareholders could reasonably interpret them as material misstatements."). Here, Plaintiff has pled that Defendants' misstatements conveyed a material misimpression that the data from the Phase I trial showed "promise" for NC318 and that the Company was moving forward to Phase II. In that regard, the statements are similar to the expression of false "hope" at issue in *Ariad*.

Indeed, the principal decision relied on by Defendants, *Kleinman v. Elan Corp., plc*, 706 F.3d 145 (2d Cir. 2013) supports Plaintiff's position. In *Kleinman,* the Second Circuit observed that the phrase "encouraging preliminary findings" could be actionable if – as is the case here – it was false and not honestly believed by Defendants. *Id*. at 153. The statement was not actionable in *Kleinman* because, in contrast to the case here, the company in that case had moved on to Phase 3 of testing "[a]t the time of the statement was made," "a step that can only be taken after there have been positive Phase 2 results sufficient to satisfy both business and regulatory interests." *Id.* On the basis of this fact, the Second Circuit held "We thus have no reason to think (nor is one

alleged) that Defendants' statements were not honestly believed." *Id.*[3] Applying *Kleinman* to this case, where Defendants pulled the Phase II trial based on the Phase I data they misleadingly touted, there is reason to believe Defendants did not believe their expressions of optimism, and so the motion to dismiss must be denied.

Further, Defendants ignore that Plaintiff has challenged other misstatements, such as Defendants' attribution of a causal link between NC318 and the remission of the NSCLC patient when such a link could not be drawn. *See supra* at Section II.E. These are statements of historical fact and are neither opinions nor puffery.

Additionally, Defendants argue that they disclosed all of the parameters of the study and so the market fully understood what was going on. *See* MTD Br. at 14-16. But that is not factually accurate or legally sufficient to avoid liability. *See, e.g.*, *SEC v. Johnston,* 986 F.3d 63, 75 (1st Cir. 2021) ("a defendants' disclosure of a subset of unfavorable facts does not prevent that defendant from misleading investors, with scienter, about another known and material unfavorable fact."). The heart of Plaintiff's case, that Defendants understood that there was no path forward to Phase II, was not disclosed at all.[4] To the contrary, Defendants repeatedly professed confidence in the Phase I data and indicated that the Company would be moving forward. ¶¶48, 51, 62, 66, 77, 151. Additionally, Defendants touted the two remissions but did not say that those two patients

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[3] The same issue was noted by the court in the second case used by Defendants: "there are no allegations that defendants did not reasonably believe" that the statements were false. *IBEW Loc. Union No. 58 Pension Tr. Fund & Annuity Fund v. Royal Bank of Scotland Grp., PLC*, 783 F.3d 383, 392 (2d Cir. 2015). Another decision, *In re GPC Biotech AG Sec. Litig.*, is not on point because the court relied on market knowledge of FDA regulatory hurdles to hold that the statements were immaterial. No. 07 CIV. 06728 (DC), 2009 WL 5125130, at *6 (S.D.N.Y. Dec. 29, 2009). That is not at issue here.

[4] Defendants incorrectly state that Plaintiff's "primary claim" relates to Defendants' selective release of data on November 5, 2019. *See* MTD Br. at 1. This misstatement is but one piece of Plaintiff's overall claim that Defendants concealed the problems with the Phase I trial that prevented progression to Phase II. Also, Defendants claim that the complaint "manufactures" certain misstatements for litigation. *Id*. at 16. That is factually incorrect and also a "red herring" argument. Plaintiff accurately quoted Defendants throughout the complaint and describes a plethora of false statements.

had not been biopsied or that the lack of biopsy rendered the data unusable. ¶¶60, 62, 67. It was not until May 29, 2020, six months after the secondary offering, that the Company began to disclose its concerns about the "heterogeneity of the patient population and lack of systemic collection" or the analytical issues caused by the lack of biopsies. *See* ¶70.

Even sophisticated individuals examining these statements could not have discerned the truth. For example, while Defendants mischaracterize Plaintiff (and her husband) as being "day trader[s]," in fact, both are well-regarded medical experts. MTD Br. at 1. Plaintiff is a published pharmaceutical research scientist with a B.S. in Pharmaceutical Sciences and two Masters of Science in Analytical Chemistry and Pharmaceutical Chemistry, while her husband serves as an attending physician in Hematology and Medical Oncology at Banner MD Anderson Cancer Center in Phoenix, Arizona. Yet, despite this scientific background, Plaintiff and her husband were deceived by Defendants' statements.

Finally, Defendants seem to argue that the decision to pull the Phase II trial was not based on the Phase I data they had in November 2019, but on subsequent biomarker analysis. *See* MTD Br. at 7. This factual dispute with the allegations of the complaint is no basis for dismissal at the pleading stage, where the allegations of the complaint are taken as true and all inferences are construed in favor of the plaintiff. *Carpenters Pension Tr. Fund of St. Louis v. Barclays PLC*, 750 F.3d 227, 235 (2d Cir. 2014) (finding "defendants' arguments here involve questions of fact and should not be resolved upon a motion to dismiss."); *SEC v. Fiore*, 416 F. Supp. 3d 306, 330 (S.D.N.Y. 2019) (holding that "a mixed question of fact and law that cannot be resolved solely from the facts alleged in the Complaint").

Moreover, Defendants' position is not persuasive. Defendants' own press release cited "current enrollment criteria and clinical response data" as the reason for the decision, not

biomarker analysis. *See* Def. Ex. L. In fact, the press release noted that "the analysis of biomarker data for these cohorts has been delayed and is not yet complete." *Id.* Coverage of the announcement interpreted Defendants as saying that "NextCure does not believe it has Phase I data that make Phase II testing worthwhile." ¶77.

2. Defendants Selectively Released Negative Data

On November 5, 2019, Defendants released an abstract that contained only some of the trial data that the Company had, painting a misleading picture of NC318's efficacy. The November 5, 2019 abstract release reported that 43 patients had been dosed with NC318 across six dose cohorts (8mg-800mg, every two weeks) in advanced solid tumors of varying types of cancer. ¶48. NextCure reported that NC318 had been well tolerated and tumor responses were evaluable in 32 patients, highlights including, one patient who achieved complete remission (a/k/a "a complete response"), another who experienced tumor shrinkage (a/k/a "a partial response") and three whose diseases appeared not to have worsened. *Id*. NextCure observed a "29% overall response rate (ORR)," and reported an "overall disease control rate (DCR) of 71%." *Id*. This was incomplete and misleading data that was material, best evidenced by the responding surge of nearly 250% of NextCure's stock price. ¶49. In fact, this great news was based on partial results since NextCure was withholding the data from the remaining 25 evaluable patients. ¶¶9, 49. Among these 25 patients were three additional NSCLC patients who showed no positive results from NC318. Consequently, among patients with NSCLC, NextCure's ORR was not 27%, but 15%, and its DCR was not 71%, but 46%. ¶49.

Defendants had a duty to disclose accurate current findings once they decided to report the partial positive data "'as a result of the ongoing duty to avoid rendering existing statements misleading by failing to disclose material facts.'" *In re BioScrip, Inc. Sec. Litig.*, 95 F. Supp. 3d 711, 727 (S.D.N.Y. 2015) (citing *In re Lululemon Sec. Litig.*, 14 F. Supp. 3d 553 (S.D.N.Y. 2014));

see also Billhofer v. Flamel Techs., SA, 663 F. Supp. 2d 288, 299 (S.D.N.Y. 2009) (even if the "[earlier] press release did not amount to a material misstatement, at the very least it created a continuing duty to disclose the CASPER results, once those results became known to [Defendant]"). As is oft repeated, "once a company speaks on an issue or topic, there is a duty to tell the whole truth," "[e]ven when there is no existing independent duty to disclose [such] information." *Meyer v. Jinkosolar Holdings Co.*, 761 F.3d 245, 250 (2d Cir. 2014). Defendants cannot present only the good results, while withholding the bad. "Statements can be misleading if they are materially untrue . . . . They can also be misleading if they are half-truths, painting a materially false picture in what they say because of what they omit." *Johnston*, 986 F.3d at 72 (finding that "a reasonable jury could find that [the defendant] used carefully crafted half-truths and distortions to convey a false understanding of the FDA's feedback on the company's clinical trial and thereby violated his duty to make accurate statements regarding material facts"). *Id* at 74. *See also In re Transkaryotic Therapies, Inc. Sec. Litig.*, 319 F. Supp. 2d 152, 159 (D. Mass. 2004) ("the facts as alleged do state a claim that TKT made material omissions in withholding the FDA's opinion that TKT's studies did not show efficacy and were methodologically flawed and that in order to generate acceptable data, TKT would have to start over from scratch.").

Defendants state NextCure "did not have the option of providing data through November because the Journal's publication schedule required submission in final format." MTD Br. at 9 n.3. But some arbitrary deadline does not excuse Defendants from their obligation under the securities laws to present accurate data to the market.

3. Defendants' Materially False Statements Relating to FIND-IO

Defendants repeatedly stated that the FIND-IO platform was designed, developed, and created by NextCure and was "***based on*** the immunological expertise of [its] management team and the scientific leadership of [its] scientific founder, Dr. Lieping Chen." ¶¶45-46, 60, 134.

Defendants continuously described the FIND-IO platform as "novel" and "proprietary" even though it was far from either. ¶¶45, 60. However, as alleged in the AC, FIND-IO was really a platform designed and created by a partner and competitor, Immunaccel. NextCure's version of the platform was built upon misappropriated confidential information and know-how from the direct competitor, through Defendant Richman's dual role on the Board of Managers of Immunaccel and President and CEO of NextCure. ¶¶4, 47. From 2013, approximately ***two years before*** he co-founded NextCure with Dr. Chen, through 2019, part of that time while he was serving on the Board of Managers of Immunaccel, Defendant Richman arranged for NextCure to become a customer of Immunaccel. ¶47. Through this relationship NextCure was able to copy Immunaccel's 3D technology and market itself in direct competition. *Id*. Thus, ***at the time of NextCure's IPO***, FIND-IO was based on misappropriated confidential (*i.e.*, unoriginal) information, expertise, and know-how from a separate competing entity. *Id.*

There is no question that these allegations about FIND-IO not being novel, proprietary, and designed by Defendant Chen, state a claim under 10b-5 because the statements were actionable. "The first part of [Rule 10b-5] unambiguously renders untrue statements of fact actionable." *Abramson v. Newlink Genetics Corp.*, 965 F.3d 165, 174 (2d Cir. 2020). The statements that FIND-IO was a proprietary and novel platform designed, developed, and created by NextCure was clearly false. Plaintiff has sufficiently alleged "an actual ***statement***" that is "untrue outright or misleading by virtue of what it omits to state." *Glob. Brokerage,* 2019 WL 1428395, at *8. *See also Youngers v. Virtus Inv. Partners Inc.*, 195 F. Supp. 3d 499, 515 (S.D.N.Y. 2016).

Defendants challenge the allegations by challenging Plaintiff's reliance on a complaint against NextCure. Defendants rely on *In re CRM Holdings, Ltd.*, for the proposition that "Second Circuit case law is clear" that a complaint cannot rely on dismissed or settled complaints in other

matters as evidence. No. 10 Civ. 975 (RPP), 2012 WL 1646888, at *26 (S.D.N.Y. May 10, 2012). However, most courts disagree with Defendants with one court indicating that "no Second Circuit precedent indicates such a broad rule." *In re OSG Sec. Litig.*, 12 F. Supp. 3d 619, 622 (S.D.N.Y. 2014); *In re Mylan N.V. Sec. Litig.*, 379 F. Supp. 3d 198, 214–15 (S.D.N.Y. 2019) (court declined to extend in *CRM Holdings*, finding that it misconstrues Circuit precedent and that "the weight of authority holds that plaintiffs may base factual allegations on complaints from other proceedings" because "'neither Circuit precedent nor logic supports . . . an absolute rule' against doing so"). *In re Netshoes Sec. Litig.*, 68 Misc.3d 788, 800, 126 N.Y.S.3d 856, 866 (N.Y. Sup. Ct. – N.Y. Cty. 2020); *OSG*, 12 F. Supp. 3d at 622; *Hunter v. Palisades Acquisition XVI, LLC*, No. 16 Civ. 8779 (ER), 2017 WL 5513636, at *10 (S.D.N.Y. Nov. 16, 2017); *Martinez v. Lvnv Funding, LLC*, No. 14-CV-00677 (RRM), 2016 WL 5719718, at *4 (E.D.N.Y. Sept. 30, 2016); *HSH Nordbank AG v. RBS Holdings USA Inc.*, No. 13 Civ. 3303 (PGG), 2015 WL 1307189, at *4 (S.D.N.Y. Mar. 23, 2015).

C. Plaintiff Adequately Alleges Scienter Against All Defendants

1. Plaintiff Has Properly Alleged Facts Showing that Defendants Knew There Was No Path Forward for NSCLC

This is a case where the inference of scienter is clear. Defendants knew that they were not going to proceed with the Phase II trial because the Phase I data showed very limited efficacy and was corrupted by the study flaws. There is no dispute that Defendants had the Phase I data and knew about the flaws in the study and its implications for Phase II at the time the statements were made. Indeed, Defendant Heller is the former Chief Medical Officer for the Company, designed the Phase I trial, and led the evaluation of the Phase I data. Under these circumstances, as many courts have found, an inference of scienter arises, largely for the same reasons underpinning falsity analysis.

"Pursuant to the PSLRA, a well-pleaded securities fraud claim must 'state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.' 'The requisite state of mind in a section 10(b) and Rule 10b–5 action is an intent 'to deceive, manipulate, or defraud.'" *Ophthotech*, 2019 WL 4464802, at *13. The question for the court is "whether ***all*** of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Tellabs*, 551 U.S. at 323-24. "The inference that the defendant acted with scienter need not be irrefutable, *i.e.*, of the 'smoking gun' genre, or even the 'most plausible of competing inferences,'" but merely "at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* at 324.

There is a strong inference of scienter where, as is the case here, Defendants make misleading statements and omissions concerning an ongoing medical trial that is at odds with information that they had access to. *See, e.g.*, *Ophthotech*, 2019 WL 4464802, at *17 (strong inference of scienter found where defendants had "in their possession" information regarding changes in trial enrollment); *Zak v. Chelsea Therapeutics Int., Ltd.*, 780 F.3d 597, 610 (4th Cir. 2015) (strong inference that defendants acted with scienter where they failed to disclose material information "while releasing less damaging information that they knew was incomplete"); *Schueneman v. Arena Pharm., Inc.*, 840 F.3d 698, 707 (9th Cir. 2016) (scienter pled where defendant had access to negative data that was found to have rendered earlier statements touting positive studies false); *Medina v. Clovis Oncology, Inc.*, 215 F. Supp. 3d 1094, 1125 (D. Colo. 2017) (same); *Yanek v. Staar Surgical Co.*, 388 F. Supp. 2d 1110, 1130 (C.D. Cal. 2005) (scienter pled by alleging facts indicating that defendants knew of undisclosed adverse information); *In re Neopharm, Inc. Sec. Litig.*, No. 02 C 2976, 2003 WL 262369, at *11 (N.D. Ill. Feb. 7, 2003)

(sufficient facts plead to illustrate an inference that defendants were aware of unfavorable test results that were "likely only in [only] the[ir] control").

Here, Plaintiff has alleged that Defendants had actual knowledge NC318 had no realistic path forward because the Phase I open-label trial was extremely small, the number of positive results was limited and the patients with the two best results were not biopsied before treatment, meaning no one could discern whether NC318 was the reason for the positive results. ¶¶56-59. As discussed *supra* in §§II.C and II.E, the AC also alleges with specificity that the ORR and DCR figures NextCure touted in the November 2019 abstract were, in fact, significantly lower ***when*** Defendants eventually disclosed all the Phase I data they possessed, rather than a seemingly positive subset. ¶¶49, 56-60. Thus, as in the forgoing decisions, there is a strong inference of scienter because Defendants were fully aware of the bad Phase I data and its meaning. And as Defendants later admitted, the Phase I data was so deficient that it necessitated complete abandonment of the Phase II trial as to NSCLC. ¶72. In the wake of that announcement, analysts concluded that NextCure had a "0%" chance of developing a monotherapy for NSCLC. ¶73. There is a strong inference of scienter where Defendants knew since at least November 2019 that the chance of developing a monotherapy of NSCLC was 0% or close to it but continually boosted the Company's stock price by professing to be encouraged by the data while selling $172 million in stock.

The strong inference of scienter is further confirmed by the factual allegations that (1) NC318 was ***the only*** product candidate from NextCure to reach clinical testing (¶5); (2) NSCLC patients represented the most commercially significant market for NC318 (¶12); (3) the Phase 1/2 Clinical trial was open-label, enabling study participants and researchers (here, NextCure) to know which treatment the patient is receiving ***and*** the outcomes of that treatment

during and throughout the course of the study (¶42); and (4) Defendant Heller, who ran the trial, left the Company when the truth about NC318 and FIND-IO was revealed and the Company's stock plummeted over 54%. ¶¶72, 78. *In re Aetna Inc. Sec. Litig.*, 34 F. Supp. 2d 935, 953 (E.D. Pa. 1999) (scienter adequately pled against high-ranking corporate officers where alleged misstatement concerned a "key aspect" of the company's business); *Medina*, 215 F. Supp. 3d at 1126-27 (plaintiffs adequately alleged scienter where defendants "continuously reviewed and analyzed" trial results, had "access to all data" including "inconsistent data" that contradicted public statements, and "gave detailed, data-laden responses to analyst questions"); *see also Webb v. Solarcity Corp.*, 884 F.3d 844, 854-55 (9th Cir. 2018) (core operations doctrine permits a court to "infer that facts critical to a business's core operations or an important transaction are known to a company's key officers").

Allegations of motive strengthen an inference of scienter. *See Ottmann v. Hanger Ortho. Group, Inc.*, 353 F.3d 338, 345 (4th Cir. 2003). Here, the AC plausibly alleges that Defendants were motivated to conceal the truth about how the Phase I data for NC318, was "unquestionably bad" because of a desire to raise capital in a secondary offering, to the tune of $172.2 million. ¶60. *Immune Response* is instructive. There, the plaintiffs alleged, as here, that the defendants knowingly (or recklessly) made reassuring statements about the efficacy of the Company's most advanced drug on secondary markers in the absence of complete data. *Immune Response Sec. Litig.*, 375 F. Supp. 2d at 1022. They also allegedly knew (or should have known) that FDA approval, at least in the projected time frame, was highly improbable. To further establish scienter, plaintiffs alleged that the Company's desire to obtain continuing financing through a $15 million secondary public offering amounted to motive. *Id.* at 1023. The court agreed and found a strong inference of scienter when it considered the offering and other allegations in the complaint as a

whole. *Id.*; *see also In re Genworth Fin. Inc. Sec. Litig.*, 103 F. Supp. 3d 759, 786 (E.D. Va. 2015) (temporal relationship between alleged false statements and bond offering supported scienter); *Medina*, 215 F. Supp. 3d at 1128 (holding that allegation that company was '"heavily dependent' upon investor capital in order to fund its operating expenses" was "a factor from which scienter may be inferred because, if true, the Clovis Defendants had a strong incentive to mislead potential investors about the efficacy and safety of rociletnib in order to attract the investors' capital").

2. Plaintiff Has Alleged Scienter with Respect to the FIND-IO Misstatements

Plaintiff has alleged scienter with respect to the FIND-IO misstatements by alleging that Defendant Richman, the Company's CEO, was the one who misappropriated its competitors' technology. ¶47. Richman was recruited to assist in building Immunaccel and served on that Company's Board. *Id.* It was Richman who began receiving Immunaccel's confidential information. *Id*. Thus, Richman had direct knowledge that the FIND-IO platform was not "proprietary" as claimed in the Company's public statements.

3. Defendants' Competing Argument on Scienter Is Factually Inaccurate

Defendants attempt to dispute Plaintiff's inference of scienter, but their arguments are easily rejected as factually incorrect.

Defendants claim that there is no inference of scienter because all of their statements were "completely accurate and directly supported by the trail results then available to NextCure." MTD Br. at 22. Wrong. As explained above, the Phase I data, combined with design flaws that corrupted the data, showed that there was no path forward on NSCLC. *See supra* at §§II.C and II.E. Defendants knew that from at least November 2019 onward, but falsely professed to be encouraged by the data and misleadingly trumpeted the supposed significance of two remissions that had no real value in demonstrating the effectiveness of NC318. *Id.*

Defendants say they disclosed all of the parameters of the trial, which "refutes" an inference of fraud. MTD Br. at 22. Wrong again. Defendants did not disclose the extent of the flaws in the study or the way that these deficiencies corrupted Phase I's data. *See supra* at §III.B. Defendants, instead, led investors to believe that the data supported moving forward to Phase II when that was not the case.

Defendants say that Plaintiff needs to plead more facts regarding her knowledge (MTD Br. at 23), but they cannot dispute that, as Plaintiff has pled, Defendants designed and ran the Phase I trial and thus knew the truth. *See supra* at §III.C.1.

Finally, with respect to motive and opportunity, Defendants say they fully disclosed everything before the secondary offering. *See* MTD Br. at 21. But again, that is factually incorrect. As Plaintiff has alleged, Defendants knew by November 2019 that NextCure was not proceeding with Phase II but pretended otherwise so that the Company could proceed with its November 18, 2019 secondary offering, which was entirely dependent on the commercial value that a NC318 treatment for NSCLC provided for the Company. *See supra* at §§II.D and II.E.

D. The Amended Complaint Adequately Alleges Securities Act Violations

Defendants' IPO and SPO were negligently prepared and riddled with false and misleading statements that provided the market, and the purchasers of shares, with an inaccurate understanding of the value of the Company, risks to the shareholders, and potential success with the new drug in testing phase in the future. The AC pleads specific claims of materially untrue statements, misleading statements and omissions relating to NextCure's defective IPO and defective SPO. *See e.g.*, ¶¶126-62. "If a plaintiff purchased a security issued pursuant to a registration statement, ***he need only show a material misstatement or omission to establish his prima facie case***. Liability

against the issuer of a security is virtually absolute even for innocent misstatements." *Herman*, 459 U.S. at 375.

The AC pleaded, in detail, that both the IPO and SPO included material misstatements and omissions about the novelty and uniqueness of NextCure's FIND-IO platform, and, of Defendant Richman's affiliation with a direct competitor, Immunaccel. ¶¶129-30, 139. The AC pleads numerous statements within the IPO and SPO where the Company described the FIND-IO as proprietary, novel, and that it was created relying on "***the TCAA, a predecessor of the FIND-IO platform that Dr. Chen used to discover the immunosuppressive properties of S15***." ¶¶134-38. However, FIND-IO was not proprietary, novel, or created relying on "***the TCAA.***" It was a copy of Immunaccel's platform.

The SPO Offering Documents continued to materially mislead the investors when NextCure announced the results from the testing. For example, NextCure stated, "***NC318 has the potential to treat multiple cancer indications***," and characterized NC318 as being "***well suited to treat patients who are not responding to PD-1/PD-L1 directed cancer therapies***." ¶151. Defendants' statements were materially misleading because the NC318 data Defendants possessed, ***at the time of the SPO***, the data showed that the Company could not proceed to Phase II for NSCLC.

These are material misstatements for the reasons discussed above. The facts in *In re Ovascience, Inc. S'holder Litig.*, illustrate a similar fact pattern to this case. In that case, plaintiffs alleged that the Registration Statement "painted" an optimistic view "regarding [a drug's] prospects as a fertility treatment, stocks prices for Ovascience briefly shot up . . . then sharply declined when the facts regarding [the drug] emerged just a few months later – facts that were known at the time the Registration Statement issued. This more than satisfies the requirement that

the Complaint set forth facts 'plausibly suggesting (not merely consistent with) an entitlement to relief.'" No. SUCV201503087BLS2, 2016 WL 8200502, at *1 (Mass. Super. Ct. – Suffolk, Dec. 22, 2016). Plaintiff in this matter is entitled to relief**.**

The failure to disclose these facts also violated the affirmative duty to disclose under Section 11 of the Securities Act. "One of the potential bases for liability under §§11 and 12(a)(2) is an omission in contravention of an affirmative legal disclosure obligation." *Panther Partners Inc. v. Ikanos Commc'ns, Inc.*, 681 F.3d 114, 120 (2d Cir. 2012). Items 303 and 503 provide the disclosure obligations. Item 303 requires disclosure of "any known trends or uncertainties" that Defendants "reasonably expect[] will have a material favorable or unfavorable impact" on sales or revenues. 17 C.F.R. §229.303(a)(3)(ii) ("Item 303"). Item 503 of SEC Regulation S-K, 17 C.F.R. §229.503(c) ("Item 503"), imposed an independent duty on Defendants to provide, among other things, a "discussion of the most significant factors that make the offering speculative or risky." Plaintiff alleges that Defendants failed their disclosure obligations under Items 303 and 503.

The IPO Offering Documents violated Item 303 by failing to disclose that, as of the IPO, NextCure had effectively copied its direct competitor's design platform and therefore, FIND-IO was not "novel," "unique," or "proprietary," exposing the Company to potential legal and reputational risks from claims by Immunaccel, and calling into question the supposed "value" of FIND-IO and NextCure. The SPO Offering Documents violated Item 303 for the same reasons and because it failed to disclose that, as of the SPO, the NC318 data Defendants possessed showed a lack of efficacy and objective response. ¶159. "These circumstances were not simply 'potentially problematic' for the Company; they were very bad." *Panther Partners,* 681 F.3d at 122.

Under Item 503, Defendants failed to disclose, at the time of the IPO, Defendants knew (or had reason to know) that FIND-IO was not as novel as they made it seem, and that, at the time of the SPO, Defendants had concerning NC318 data. Although Defendants point to general risk warnings, none are specific or accurate. "In other words, the Prospectus' disclosure was not 'specific enough to warrant a reasonable investor's attention.'" *McKenna v. SMART Techs. Inc.*, No. 11 Civ. 7673 (KBF), 2012 WL 3589655, at *6 (S.D.N.Y. Aug. 21, 2012).

The risk disclosures in the Offering Documents were not effective because they only warned of potential liabilities to any company in high-tech development and design, not the specific issues the company knew it was facing because of its own actions at the time the statements were made. For example, in the IPO, Defendants warned, "***Our competitors may also develop drugs or discovery platforms that are more effective, more convenient, more widely used or less costly than our product candidates or our FIND-IO platform***," when they knew and were partnered with a competitor who had actually created the proprietary system and was in direct competition with NextCure. ¶144.

E. Plaintiff Adequately Pled Section 20(a) and Section 15 Control Liability Claims

Plaintiff had adequately pled "control person" violations under Section 20(a) of the Exchange Act and Section 15 of the Securities Act. Plaintiff had plead primary disclosure violations and control by Defendants. ¶¶16-17, 30, 175-178.

CONCLUSION

For the foregoing reasons, the Court should deny Defendants' Motion to Dismiss.

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